

Sarah Abbie Collins, M.D.

Page 1

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

3 -----) Master File No.
4 IN RE: ETHICON, INC.,) 2:12-MD-02327
5 PELVIC REPAIR SYSTEM)
6 PRODUCTS LIABILITY) MDL 2327
7 LITIGATION)
8 -----) JOSEPH R. GOODWIN
9) U.S. DISTRICT JUDGE

10 THIS DOCUMENT RELATES TO)
11 ALL WAVE 4 AND SUBSEQUENT)
12 WAVE CASES AND)
13 PLAINTIFFS:)

14 Sharon Bartley)
15 Case No. 2:12cv04270)

16 Gladys Thruman)
17 Case No. 2:12cv04930)

18 Sharon Kay Lunsford)
19 Case No. 2:12cv03308)

20 Bertha Towns)
21 Case No. 2:12cv03306)

22 Peggy Connolly)
23 Case No. 2:12cv04026)
24 -----)

17 GENERAL EXPERT DEPOSITION OF
18 SARAH ABBIE COLLINS, M.D.
19 **TVT and TVT Exact**
20

21 March 6, 2017
22 Chicago, Illinois
23
24

Golkow Technologies, Inc - 877.370.3377

EXHIBIT A

Sarah Abbie Collins, M.D.

<p style="text-align: right;">Page 2</p> <p>1 2 3 4 The TVT and TVT Exact general expert 5 deposition of SARAH ABBIE COLLINS, M.D., called by 6 the Plaintiffs for examination, taken pursuant to 7 the Federal Rules of Civil Procedure of the United 8 States District Courts pertaining to the taking of 9 depositions, taken before CORINNE T. MARUT, C.S.R. 10 No. 84-1968, Registered Professional Reporter and a 11 Certified Shorthand Reporter of the State of 12 Illinois, at the offices of Kirkland & Ellis LLP, 13 Suite 700, 300 North LaSalle Street, Chicago, 14 Illinois, on March 6, 2017, commencing at 9:04 p.m. 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 4</p> <p>1 INDEX 2 GENERAL EXPERT DEPOSITION 3 TESTIMONY IN RE TVT - Pages 1 to 182 4 TESTIMONY IN RE TVT EXACT - Pages 182 to 331 5 Some areas of testimony re TVT and TVT Exact 6 overlap per statement of counsel - Page 182 7 SARAH ABBIE COLLINS, M.D. EXAMINATION 8 BY MS. LIU..... 5 9 BY MR. RUMANEK..... 296 10 BY MS. LIU..... 315 11 BY MR. RUMANEK..... 323 12 BY MS. LIU..... 328 13 BY MR. RUMANEK..... 329 14 BY MS. LIU..... 330 15 16 EXHIBITS 17 COLLINS (TVT/TVT EXACT) EXHIBIT MARKED FOR ID 18 No. 1 Notice to Take Deposition of 5 19 Sarah Collins, MD 20 21 No. 2 Invoice as of 1/29/17 21 22 23 No. 3 Curriculum Vitae 30 24 25 No. 4 Expert Report of Sarah 113 26 Collins, M.D., TVT and TVT Exact 27 No. 5 Sarah Collins General Reliance 134 28 List, MDL Wave 4 29 30 No. 6 Sarah Collins Supplemental 134 31 Reliance List MDL Wave 4 32 No. 7 Thumb drive containing 183 33 reliance materials 34</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: 2 ON BEHALF OF THE PLAINTIFF: 3 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 4 17 East Main Street 5 Suite 200 6 Pensacola, Florida 32502 7 850-202-1010 8 BY: MARY LIU, ESQ. 9 mliu@awkolaw.com 10 11 ON BEHALF OF THE DEFENDANTS: 12 TROUTMAN SANDERS LLP 13 Bank of America Plaza 14 600 Peachtree Street, N.E. 15 Suite 5200 16 Atlanta, Georgia 30308-2216 17 404-885-2606 18 BY: ERIC RUMANEK, ESQ. 19 eric.rumanek@troutmansanders.com 20 21 REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 (WHEREUPON, the witness was duly 2 sworn.) 3 SARAH ABBIE COLLINS, M.D., 4 called as a witness herein, having been first duly 5 sworn, was examined and testified as follows: 6 EXAMINATION 7 BY MS. LIU: 8 Q. Good morning, Dr. Collins. 9 A. Good morning. 10 Q. For the record can you please state your 11 full name. 12 A. Sarah Abbie Collins. 13 Q. And what is your address for your place 14 of practice? 15 A. 250 East Superior Street, Suite 52370, 16 Chicago, Illinois, 60611. 17 Q. Doctor, I am going to hand you real 18 quickly the Notice for Deposition. 19 MS. LIU: Counsel. 20 (WHEREUPON, a certain document was 21 marked Collins (General TVT/TVT 22 Exact) Exhibit No. 1, Notice to 23 Take Deposition of Sarah Collins, 24 MD.)</p>

2 (Pages 2 to 5)

Sarah Abbie Collins, M.D.

<p style="text-align: right;">Page 26</p> <p>1 report that I did I got a little faster. So, like 2 20 for two and then another... 3 Maybe 30 hours, 30 to 35. 4 BY MS. LIU: 5 Q. And, Doctor, you said that you served in 6 five of the cases, served a report in five of the 7 cases. Did you actually draft a report for the 8 other two? 9 A. The other four? 10 Q. You mentioned you had seven. You were 11 asked to do seven. 12 A. Oh. The other two. I see. 13 No, I did not. I didn't actually look 14 at those reports at all. 15 Q. So, you did a total of five reports, 16 case-specific reports? 17 A. Um-hmm. 18 MR. RUMANEK: Yes? 19 BY THE WITNESS: 20 A. Yes. 21 MS. LIU: Thank you. 22 BY MS. LIU: 23 Q. Doctor, is this the first time you've 24 been asked by a medical device company to serve as</p>	<p style="text-align: right;">Page 28</p> <p>1 A. It was during both. 2 Q. Can you -- would you be able to decipher 3 between how many were done in residency and how 4 many were done during your fellowship? 5 A. Honestly, no. I don't think I could. 6 You know, in fellowship, we were doing a lot of 7 transobturator and retropubic slings. Every 8 retropubic sling was the original TVT Retropubic 9 and I did -- I would say many more were from 10 fellowship than were from residency. 11 In residency it's not uncommon for the 12 attendings and fellows to not necessarily let the 13 resident pass the trocar. So, I probably did 10 to 14 20, but these are numbers that I'm kind of, you 15 know, just pulling out from, you know, my 16 recognition of the -- the way that training 17 normally goes. 18 And in fellowship I probably did 80, and 19 I did many more than that of transobturator slings 20 too. 21 Q. And, Doctor, just so you understand, I 22 don't need an exact number and I don't want you to 23 guess, but I am entitled to a fair estimate. 24 So, based on your recollection, if you</p>
<p style="text-align: right;">Page 27</p> <p>1 an expert? 2 A. Yes. 3 Q. So, you've never been asked by another 4 medical device company and turned them down, is 5 that correct? 6 A. That's correct. 7 Q. Doctor, I'm going to ask you right now 8 about your experience with the TVT Retropubic and 9 not the TVT Exact just yet. 10 A. Okay. 11 Q. How many TVT Retropubics have you 12 implanted? 13 A. The TVT Retropubics that I implanted 14 were all done during training and I can't give you 15 an exact number, but I would say about 100. 16 Q. And when you said "training," I saw that 17 on your background you were a fellow for a little 18 while and then you also had your residency. So, 19 when was this training, the TVT Retropubic 20 training? 21 A. That would have been between 2003 and 22 2011. 23 Q. Was it during one of your -- was it 24 during your residency or your fellowship?</p>	<p style="text-align: right;">Page 29</p> <p>1 can have a number that is a fair recollection of 2 what you remember, then I would appreciate that. 3 So, thank you very much. 4 Now, you mentioned that in residency 5 they didn't -- the attendings didn't let the 6 residents pass a trocar or do that portion of the 7 procedure. 8 In these 10 to 20 that you mentioned, 9 were these the ones where you actually performed 10 the procedure or were you just assisting the 11 attending? 12 A. No, those have been ones where I 13 actually passed the trocars. 14 Q. In fellowship, the 80 were ones that you 15 actually passed the trocars as well? 16 A. Yes. 17 Q. Thank you, Doctor. 18 Why have you not used the TVT Retropubic 19 since fellowship? 20 A. Mainly because I used the TVT Exact when 21 I became an attending. It became readily 22 available. It was the sling that my group was 23 using and I found that I liked it a lot. 24 Q. You liked it better than you liked the</p>

8 (Pages 26 to 29)

Sarah Abbie Collins, M.D.

<p style="text-align: right;">Page 30</p> <p>1 TVT Retropubic?</p> <p>2 MR. RUMANEK: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No. I didn't necessarily like it</p> <p>5 better, but I certainly found that I could use it</p> <p>6 well and accomplish the same operation using the</p> <p>7 TVT Exact.</p> <p>8 So, sometimes it just makes sense to,</p> <p>9 you know, conform to the, you know, the -- what the</p> <p>10 group is doing in terms of, you know, our stock of</p> <p>11 the sling and what we have. We can only buy one.</p> <p>12 So, to me it made perfect sense to use the</p> <p>13 TVT Exact.</p> <p>14 Q. Doctor, you mentioned -- since you</p> <p>15 mentioned your group, let me go ahead and switch</p> <p>16 gears a little bit.</p> <p>17 I am handing you what I have marked as</p> <p>18 Exhibit 3.</p> <p>19 (WHEREUPON, a certain document was</p> <p>20 marked Collins (General TVT/TVT</p> <p>21 Exact) Exhibit No. 3, Curriculum</p> <p>22 Vitae.)</p> <p>23 THE WITNESS: Do you want this back?</p> <p>24 MS. LIU: Yes. Let's go ahead and put this</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. Based on your CV, you joined this group</p> <p>2 in June 2016, correct?</p> <p>3 A. Correct.</p> <p>4 Q. So, prior to that, you were with the</p> <p>5 University of Chicago?</p> <p>6 A. Correct.</p> <p>7 Q. In their Ob-Gyn practice?</p> <p>8 A. Correct.</p> <p>9 Q. Were you also working in female pelvic</p> <p>10 medicine and reconstructive surgery with University</p> <p>11 of Chicago?</p> <p>12 A. Yes. The practice was called gynecology</p> <p>13 and reconstructive pelvic surgery, but it was</p> <p>14 FPMRS.</p> <p>15 Q. That was from August 2011 to May 2016,</p> <p>16 is that correct?</p> <p>17 A. Correct.</p> <p>18 Q. When did you finish your fellowship?</p> <p>19 A. In the end of June 2011.</p> <p>20 Q. And then you moved to Chicago from that</p> <p>21 point forward, is that correct?</p> <p>22 A. Correct.</p> <p>23 Q. Now, when you mentioned the group used</p> <p>24 TVT Exact, are you talking about the University of</p>
<p style="text-align: right;">Page 31</p> <p>1 back here.</p> <p>2 MR. RUMANEK: Do you need the Notice anymore?</p> <p>3 MS. LIU: No.</p> <p>4 MR. RUMANEK: Let's keep it stacked for the</p> <p>5 Court Reporter.</p> <p>6 BY MS. LIU:</p> <p>7 Q. Doctor, I have handed to you what I have</p> <p>8 marked as Exhibit 3. Do you recognize that</p> <p>9 document?</p> <p>10 A. Yes.</p> <p>11 Q. It's your CV, is that correct?</p> <p>12 A. Yes.</p> <p>13 Q. Doctor, you mentioned your group. What</p> <p>14 is the group that you are currently with?</p> <p>15 A. I'm with Northwestern Medicine at this</p> <p>16 time.</p> <p>17 Q. And is it a specific urogynecology group</p> <p>18 that you're with?</p> <p>19 A. Yes.</p> <p>20 Q. Can you explain how that works?</p> <p>21 A. I am part of a university-based female</p> <p>22 pelvic medicine and reconstructive surgery practice</p> <p>23 at Northwestern University. We all have university</p> <p>24 appointments as well as clinical responsibilities.</p>	<p style="text-align: right;">Page 33</p> <p>1 Chicago?</p> <p>2 A. Yes.</p> <p>3 Q. Now, since you've joined Northwestern</p> <p>4 does your current group also use TVT Exact?</p> <p>5 A. No. We use the Boston Scientific</p> <p>6 Advantage Fit.</p> <p>7 Q. And, Doctor, is that what you are</p> <p>8 currently using, the Advantage Fit?</p> <p>9 A. Yes.</p> <p>10 Q. Since June of 2016?</p> <p>11 A. Yes.</p> <p>12 Q. Who makes that decision in your group?</p> <p>13 A. It's a decision made between our</p> <p>14 division director and operative -- OR purchasing.</p> <p>15 Typically the vendors have package deals with the</p> <p>16 hospital and, you know, certainly the clinicians</p> <p>17 have input about which devices get purchased and</p> <p>18 used regularly. But, yeah, that decision had</p> <p>19 actually already been made when I joined the group.</p> <p>20 Q. Have you made any suggestions to switch</p> <p>21 to TVT or TVT Exact?</p> <p>22 A. Honestly, no. I find the two devices</p> <p>23 clinically almost identical.</p> <p>24 Q. Which two devices are you talking about?</p>

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Sarah Abbie Collins, M.D.

<p style="text-align: right;">Page 38</p> <p>1 passed from the paraurethral dissection to the 2 medial thigh. 3 Q. And, Doctor, can you estimate the number 4 of TOT approaches versus retropubic approaches that 5 you have performed personally? 6 A. I'd say if you were to tally it up right 7 now, maybe half and half in my -- well, actually, I 8 might correct that and say I've done more 9 retropubics at this point. 10 In my fellowship we did more 11 transobturator. But pretty soon after my 12 fellowship, when I became an attending, I started 13 to do more retropubics and now I almost exclusively 14 do retropubics. 15 Q. And why is that? 16 A. Some of the longer term data comparing 17 retropubic and transobturator slings indicate that 18 the retropubic slings may be more effective. 19 Q. So, you've -- you've determined that you 20 want to do the retropubic approach over the 21 transobturator approach, is that correct? 22 A. Most of the time. Not exclusively, but 23 most of the time. 24 Q. What percentage currently?</p>	<p style="text-align: right;">Page 40</p> <p>1 rep. 2 Q. Do you remember any Ethicon reps? 3 A. No. 4 Q. And, Doctor, how many -- let me break 5 this down actually. 6 How many slings have you implanted since 7 you've joined the practice at Northwestern? 8 A. I don't know. Maybe -- I've been there 9 less than a year. Sort of getting ramped up now 10 volume-wise. I would say 50. 11 Q. So, you implant around 50 slings at 12 Northwestern. What about during your time at 13 University of Chicago? 14 A. A lot more. Maybe 200. 15 Q. And then what about during your 16 fellowship? 17 A. I think I already gave you that number. 18 Q. Total between all of your slings. 19 A. Oh. Well, I think I told you about 80 20 retropubics and I would say for the Monarcs maybe 21 250. So, maybe 300, what is that, 330, something 22 like that. 23 MR. RUMANEK: Don't ask a lawyer to do math. 24 MS. LIU: That part is so true.</p>
<p style="text-align: right;">Page 39</p> <p>1 A. I would say 95% retropubic. 2 Q. And when you currently do do the 3 transobturator approach, do you still use the 4 Monarc sling? 5 A. The Monarc sling is no longer available. 6 Q. Which sling do you use now? 7 A. You know what? I can't remember the 8 name of it, which sounds ridiculous. I think it 9 might be -- I think it's the Obtryx. I can 10 describe the device to you perfectly but I -- 11 Q. Is it a Boston Scientific product? 12 A. Yeah. I think so. 13 Q. At your current practice are they using 14 Boston Scientific exclusively? 15 A. I don't know. 16 Q. Doctor, in your career as a surgeon have 17 you been visited by sales reps? 18 A. Yes. 19 Q. Sales reps for Ethicon? 20 A. I don't know. Maybe very early on in 21 my -- maybe in my residency. It's hard to say. By 22 the time I was in fellowship, TVT was so well 23 incorporated into our practice that I don't know 24 that there would have been a role for an Ethicon</p>	<p style="text-align: right;">Page 41</p> <p>1 BY MS. LIU: 2 Q. What about during your residency, you 3 said residency wasn't that many, is that correct? 4 A. No, I would say 30 absolute max but 5 somewhere between 10 and 30 for all in. 6 Q. So, in doing this math, we're looking at 7 maybe around 600 total slings implanted during your 8 career, is that correct? 9 A. Probably. 10 MR. RUMANEK: Just so it's clear, you're 11 referencing polypropylene slings, correct? 12 MS. LIU: Correct. 13 BY MS. LIU: 14 Q. Is that -- 15 A. Yeah. 16 Q. -- what you're -- 17 A. Yes. 18 Q. The numbers that you gave me were 19 polypropylene slings? 20 A. Yes. 21 Q. So, 600 polypropylene slings during your 22 career. Have you followed every single one of your 23 patients that you've implanted a sling in? 24 A. I mean, I have seen all of my</p>

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<p style="text-align: right;">Page 58</p> <p>1 meetings about monthly.</p> <p>2 Q. And what committee are you with him on?</p> <p>3 A. I'm on the Clinical Guidelines Committee</p> <p>4 of the American Urogynecologic Society.</p> <p>5 Q. Is that AUGS?</p> <p>6 A. Yeah.</p> <p>7 Q. And what does this Clinical Guidelines</p> <p>8 Committee do?</p> <p>9 A. We usually under the direction of the</p> <p>10 Board of the American Urogynecologic Society draft</p> <p>11 documents under certain clinical headings that we</p> <p>12 feel need such a document, and essentially we</p> <p>13 review the evidence extensively and produce usually</p> <p>14 an expert opinion level document on a certain</p> <p>15 topic. It will be evidence-based, but it wouldn't</p> <p>16 fit criteria for like a meta-analysis, for example.</p> <p>17 Q. So, it would not be a peer-reviewed</p> <p>18 document, is that correct?</p> <p>19 A. Well, no.</p> <p>20 MR. RUMANNEK: Object to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Okay. No, that's not correct. They are</p> <p>23 peer-reviewed and typically do get published. I</p> <p>24 only mean to say that they're not meta-analyses,</p>	<p style="text-align: right;">Page 60</p> <p>1 up of anywhere from two to four people and they're</p> <p>2 supposed to -- typically there's a lead writer, not</p> <p>3 always but typically, and then the next step is</p> <p>4 that outlines are created for what's going to be</p> <p>5 included in the document along with a review of the</p> <p>6 literature.</p> <p>7 Then once the group approves the</p> <p>8 outlines and, you know, feels that the outline will</p> <p>9 satisfy the breadth of what we're being asked to</p> <p>10 do, writing happens and then usually have about, I</p> <p>11 don't know, four to six weeks to do the writing,</p> <p>12 maybe even more, and then we submit the document to</p> <p>13 the whole group.</p> <p>14 The whole group reviews it. Changes are</p> <p>15 made based on the group's feedback. And then there</p> <p>16 are readers then that actually handle the document</p> <p>17 outside of the group, and those are on the</p> <p>18 Terminology Committee.</p> <p>19 We have a separate Terminology Committee</p> <p>20 of AUGS, and I'm actually a liaison to that</p> <p>21 committee from the Clinical Guidelines Committee.</p> <p>22 So, we'll review the document through</p> <p>23 that committee, make sure that the terminology used</p> <p>24 in the document is consistent, and then at some</p>
<p style="text-align: right;">Page 59</p> <p>1 which is a different type of --</p> <p>2 BY MS. LIU:</p> <p>3 Q. Can you explain what that means?</p> <p>4 A. A meta-analysis is a very rigorous</p> <p>5 evaluation of multiple pieces of evidence, usually</p> <p>6 multiple articles addressing the same problem.</p> <p>7 There is a combination of the data that is done</p> <p>8 through a very rigorous analytic process that</p> <p>9 requires some extensive knowledge in specifically</p> <p>10 performing meta-analyses.</p> <p>11 Q. Doctor, how many people are in this</p> <p>12 Clinical Guidelines Committee?</p> <p>13 A. Probably about a dozen.</p> <p>14 Q. And prior to any documents being</p> <p>15 published, what process does it go through?</p> <p>16 MR. RUMANNEK: Object to the form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Well, we decide on a topic as a group.</p> <p>19 Dr. Tulikangas who is the chair of the group will</p> <p>20 be leading our meetings and we form writing groups.</p> <p>21 So, people will either request to be on a</p> <p>22 particular writing group or be asked to be on the</p> <p>23 writing group.</p> <p>24 Typically the writing group will be made</p>	<p style="text-align: right;">Page 61</p> <p>1 point after that we will release the document to</p> <p>2 the Board members and to ultimately the membership</p> <p>3 at large of AUGS.</p> <p>4 So, we get feedback from a lot of</p> <p>5 different people and then we finalize the document</p> <p>6 and publish it.</p> <p>7 Q. Now, when you -- when you talked about</p> <p>8 the topics, who decides on the topics?</p> <p>9 A. Like I said, a lot of times the Board of</p> <p>10 the American Urogynecologic Society. Anyone can</p> <p>11 raise a topic that they think might be of interest.</p> <p>12 And then usually before we put a lot of man-hours</p> <p>13 into it, we will discuss it with the Board and make</p> <p>14 sure that we feel there is a broad enough audience</p> <p>15 for it.</p> <p>16 Q. And how many people are on the Board?</p> <p>17 A. I don't know actually.</p> <p>18 Q. So, these topics that are brought in</p> <p>19 your monthly meetings, they're topics that are</p> <p>20 given to you guys by the Board, is that what I'm</p> <p>21 understanding?</p> <p>22 MR. RUMANNEK: Object to the form;</p> <p>23 mischaracterizes the testimony.</p> <p>24 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 62</p> <p>1 A. Like I said, sometimes. But like I said 2 also, anybody who has a good idea can raise that. 3 BY MS. LIU: 4 Q. And then ultimately who decides on what 5 topics each of these writing groups work on? 6 A. Well, if we've decided as a group to 7 take on a document, then it's usually, you know, a 8 conference call that we'll be having and 9 Dr. Tulikangas will say, "Who wants to participate 10 in this?" A few people will step up. 11 Q. So, who ultimately decides -- strike 12 that. 13 Does your group of 12 people decide on a 14 topic or topics to write on? 15 A. I feel like I've answered this already. 16 But essentially, I mean, sometimes Paul Tulikangas 17 will say, "The Board has mentioned that they would 18 like a document on X" or "I had a conversation with 19 a colleague the other day and they mentioned it 20 would be nice to have a document on Y." Anyone in 21 the group could say that. 22 Q. And do you -- when somebody mentions, 23 "Okay, somebody would like a topic on this" or "a 24 topic on that," is that the time where you guys</p>	<p style="text-align: right;">Page 64</p> <p>1 systematic review. We think we could offer XYZ." 2 And the group decides. 3 Q. Is it a vote? 4 A. Yeah, more or less. Usually we don't 5 even have to do like a formal vote. It's more like 6 a -- there is a tone. 7 Q. So, it's more of you guys have a 8 discussion and ultimately decide to do it without a 9 vote? 10 MR. RUMANEK: Object to the form. 11 BY THE WITNESS: 12 A. Well, I mean, when you have 12 people, 13 it's usually pretty obvious whether everybody 14 agrees or not and it rarely comes down to six -- I 15 don't think it's ever happened that six people want 16 it and six people don't. So, a vote is just not 17 really necessary. 18 BY MS. LIU: 19 Q. Is it usually unanimous when you guys 20 decide -- 21 A. Yeah. 22 Q. -- to do a project? 23 MR. RUMANEK: I note that we have been going 24 over an hour. I don't know if this is a good spot.</p>
<p style="text-align: right;">Page 63</p> <p>1 decide, yes, we are going to do it? 2 A. Yes. 3 Q. Or how does that process work is what I 4 am asking. How does the process from the time 5 somebody mentions, "Hey, this would be a great 6 topic" to ultimately deciding to work on that 7 topic? 8 A. I mean, we have these meetings monthly. 9 Typically the ideas come from some conversation in 10 the last month that people have had because we do 11 it every call. So, I would say it takes about a 12 month to decide. 13 But it could be something like, you 14 know, "Hey, we, you know -- I was speaking with 15 somebody on the Board. They'd love to have a 16 document on the efficacy of the anterior repair, 17 native tissue anterior repair. What do you guys 18 think?" 19 And we'd say, "Well, there is already a 20 systematic review on that, like XYZ. I don't know 21 if there is a role for that kind of document in the 22 literature at this point," one person may say. 23 And the other would say, "Well, you 24 know, a couple new things have come out since X</p>	<p style="text-align: right;">Page 65</p> <p>1 MS. LIU: Let's take a break. 2 (WHEREUPON, a recess was had 3 from 10:10 to 10:20 a.m.) 4 BY MS. LIU: 5 Q. Doctor, we were just talking about the 6 committee that you serve on with AUGS. 7 A. Yes. 8 Q. And you had mentioned that 9 Dr. Tulikangas is the chair of that committee. Do 10 you know how long he's been the chair? 11 A. I think he's been the chair for over a 12 year. 13 Q. And has he been on that committee prior 14 to being a chair? 15 A. I don't know that. 16 Q. And he was your fellowship director? 17 A. Correct. 18 Q. And so how -- what was the relationship 19 between a fellow and the fellowship director at the 20 program that you were at? 21 A. The fellowship director is often a 22 mentor to the fellows that are going through at 23 that time. Usually the fellowship director has a 24 bit of a stronger relationship with the fellows</p>

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<p style="text-align: right;">Page 118</p> <p>1 A. Again, the surgery to place a TVT can 2 cause that complication, but the TVT itself cannot. 3 BY MS. LIU: 4 Q. Do you agree that patients being placed 5 with TVT have the risk of having multiple revision 6 surgeries? 7 A. There is a small risk that patients will 8 require a revision surgery after any surgery for 9 stress urinary incontinence, yes. 10 Q. Now, Doctor, in your report, you had 11 talked about the risks of the 2015 IFU, is that 12 correct? 13 A. That is correct. 14 Q. And, Doctor, you haven't used the TVT 15 since 2011, is that correct? 16 A. The TVT Retropubic. 17 Q. Yes. 18 A. I've just used the TVT Exact, that's 19 correct. 20 Q. Correct. So, and when you talked about 21 the 2015 IFU, were you talking about the 22 TVT Retropubic or the TVT Exact? 23 MR. RUMANEK: Object to the form. 24 BY THE WITNESS:</p>	<p style="text-align: right;">Page 120</p> <p>1 would be done for stress incontinence. 2 BY MS. LIU: 3 Q. And, Doctor, did you review the IFUs 4 besides the 2015 one for this report? 5 A. I reviewed one other version, but I 6 can't tell you specifically which one or whether it 7 was TVT or TVT Exact that I read that. 8 Q. So, you read two IFUs in preparing your 9 report, is that correct? 10 A. Yes. 11 Q. And the two IFUs that you read, you 12 don't -- besides the 2015, you don't know which 13 other one that you read, is that correct? 14 A. Correct, but I think it was an earlier 15 version. 16 Q. Do you know how far back? 17 A. No. 18 Q. Now, do you know why the earlier 19 versions would not include all of the complications 20 that are listed in the 2015 IFU? 21 MR. RUMANEK: Object to the form. 22 BY THE WITNESS: 23 A. You know, other than sort of, you know, 24 trying to be more proactively defensive, no.</p>
<p style="text-align: right;">Page 119</p> <p>1 A. I would have been referring to both of 2 them. 3 BY MS. LIU: 4 Q. And do you agree that all the things 5 that I just listed that some of which you agreed 6 and some of which that you did not agree with are 7 in the 2015 IFU? 8 A. Do I believe -- 9 MR. RUMANEK: Object to the form. 10 BY THE WITNESS: 11 A. -- that all of the complications that 12 you listed are in the -- I think that the IFU 13 refers to the body of possible complications that 14 any surgeon trained in anti-incontinence surgery 15 would know already. 16 BY MS. LIU: 17 Q. So, you don't believe that what's in the 18 IFU is specific to the TVT? 19 MR. RUMANEK: Object to form. 20 BY THE WITNESS: 21 A. I think that a lot of it as it relates 22 to the type of mesh, you know, the Type 1 23 polypropylene, is specific to the TVT but much of 24 it is actually just referring to any surgery that</p>	<p style="text-align: right;">Page 121</p> <p>1 BY MS. LIU: 2 Q. And do you believe that all risks should 3 be in an IFU? 4 MR. RUMANEK: Object to the form. 5 BY THE WITNESS: 6 A. I think it's irrelevant whether all 7 risks are in the IFU. 8 BY MS. LIU: 9 Q. So, you don't believe that all risks 10 should be in an IFU? 11 MR. RUMANEK: Object to the form. 12 BY THE WITNESS: 13 A. I think that's correct, yes. 14 BY MS. LIU: 15 Q. Now, Doctor, have you ever designed a 16 medical device? 17 A. I've never designed a medical device. 18 Q. Have you ever drafted an IFU? 19 A. I have not. 20 Q. Do you understand the regulations that 21 are involved in drafting an IFU? 22 MR. RUMANEK: Object to the form. 23 BY THE WITNESS: 24 A. I am very vaguely aware of them but...</p>

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<p style="text-align: right;">Page 122</p> <p>1 BY MS. LIU: 2 Q. So, you don't know as far as the 3 regulations are concerned what needs to be in an 4 IFU, is that correct? 5 MR. RUMANEK: Object to the form. 6 BY THE WITNESS: 7 A. That's correct. I approach an IFU as a 8 clinician and a surgeon. 9 BY MS. LIU: 10 Q. But not as somebody who would understand 11 the regulatory restrictions or regulatory 12 requirements of an IFU, is that correct? 13 MR. RUMANEK: Object to the form. 14 BY THE WITNESS: 15 A. Probably, although I think the IFU is 16 written for me as a surgeon. I think that I'm the 17 target audience and so insofar as the, you know -- 18 I think it doesn't necessarily matter what, you 19 know, regulatory bodies would think should go in an 20 IFU. If it doesn't help me, I don't know that it's 21 relevant. 22 BY MS. LIU: 23 Q. So, if there are regulatory requirements 24 put down by the Government, you don't believe that</p>	<p style="text-align: right;">Page 124</p> <p>1 Q. So, you haven't been consulted by a 2 medical device company as to what should go in from 3 a clinician's perspective into an IFU, have you? 4 A. No. 5 Q. And as far as designing a medical 6 device, you testified that you have not, is that 7 correct? 8 A. That's correct. 9 Q. Have you ever participated in designing 10 a mesh product? 11 A. No. 12 Q. Have you ever been approached by a 13 company to help with designing a mesh product? 14 A. No. 15 Q. So, Doctor, you are not a biomaterials 16 engineer, are you? 17 MR. RUMANEK: Object to the form. 18 BY THE WITNESS: 19 A. I am not an engineer. 20 BY MS. LIU: 21 Q. And you wouldn't consider yourself to be 22 a biomechanical engineer, is that correct? 23 MR. RUMANEK: Object to the form. 24 BY THE WITNESS:</p>
<p style="text-align: right;">Page 123</p> <p>1 the medical device company should follow those 2 regulations? 3 MR. RUMANEK: Object to the form, grossly 4 mischaracterizes her testimony. 5 BY THE WITNESS: 6 A. I mean, I think that the device company 7 better follow the rules so that it doesn't get in 8 trouble. But as it relates to my practice, it 9 wouldn't make a difference. 10 BY MS. LIU: 11 Q. But you don't have any experience 12 yourself in drafting an IFU? 13 A. That's correct. 14 Q. And would you consider yourself an 15 expert when it comes to drafting an IFU? 16 MR. RUMANEK: Object to the form. 17 BY THE WITNESS: 18 A. To drafting an IFU? 19 BY MS. LIU: 20 Q. Correct. 21 A. No, I would not. 22 Q. Have you ever provided any input in 23 drafting an IFU? 24 A. I have not.</p>	<p style="text-align: right;">Page 125</p> <p>1 A. I think it's factual that I am not a 2 biomechanical engineer. 3 BY MS. LIU: 4 Q. And you are not an expert in designing 5 mesh products, is that correct? 6 MR. RUMANEK: Object to the form of the 7 question. 8 BY THE WITNESS: 9 A. I would say as it relates to 10 urogynecology, I'm an expert in the mesh products 11 that are used for urogynecology. 12 BY MS. LIU: 13 Q. But you're not an expert in actually 14 designing the weave of the mesh, is that correct? 15 MR. RUMANEK: Object to the form. 16 BY THE WITNESS: 17 A. That's correct. 18 BY MS. LIU: 19 Q. Are you an expert when it comes to 20 developing the weight of the mesh? 21 MR. RUMANEK: Object to the form. 22 BY THE WITNESS: 23 A. I am not an expert in developing the 24 weight of the mesh.</p>

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<p style="text-align: right;">Page 126</p> <p>1 BY MS. LIU: 2 Q. What about in determining the pore size, 3 are you an expert in determining the pore size of 4 the mesh? 5 MR. RUMANEK: Object to the form. 6 BY THE WITNESS: 7 A. No. 8 BY MS. LIU: 9 Q. Do you know what the optimal pore size 10 should be in a sling? 11 MR. RUMANEK: Object to the form. 12 BY THE WITNESS: 13 A. Yes. 14 BY MS. LIU: 15 Q. And how do you know that? 16 A. Well, there have been multiple studies 17 comparing different materials used for midurethral 18 slings and over the years we've attained a lot of 19 good data from the hernia literature as well and we 20 know that tissue ingrowth is maximized when the 21 pores are over 75 microns and when the mesh is 22 monofilamentous and that is an Amid Type 1 mesh. 23 Q. So, you're basing this on the Amid 24 study, is that correct?</p>	<p style="text-align: right;">Page 128</p> <p>1 familiar with? I know you mentioned the Gynemesh. 2 You mentioned the midurethral slings. You've also 3 mentioned the IntePro Y mesh. Are you familiar 4 with any other mesh products? 5 MR. RUMANEK: Object to the form. She's 6 testified about a lot of other products other than 7 just those ones that you just mentioned and she 8 also mentioned that she had used a lot of other 9 products that she couldn't specifically remember. 10 BY MS. LIU: 11 Q. Doctor, you've testified that you've 12 used multiple different products. I understand 13 that. I'm taking -- I'm putting slings in one 14 bucket right now. 15 The other sacral colpopexy meshes that 16 you have used, which ones are you most familiar 17 with? Which ones are you familiar with at all 18 actually? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. Well, the Gynemesh initial sheets that 22 we used to cut into Ys, the IntePro Y mesh, Alyte. 23 And then what we're using now is the Boston 24 Scientific mesh, and I can't remember the brand</p>
<p style="text-align: right;">Page 127</p> <p>1 MR. RUMANEK: Object to the form. 2 BY THE WITNESS: 3 A. Well, the Amid study is one, but there 4 are actually a lot of studies that have included, 5 you know, slings that have been made of other 6 materials as well and we know the outcomes of some 7 of the meshes that were used before the Amid 8 Type 1s. 9 BY MS. LIU: 10 Q. So, now -- 11 A. And now we know -- 12 Q. Sorry. 13 A. Sorry. And now we know, we have a lot 14 of data from the Amid Type 1s as well. 15 Q. So, now, Doctor, have you compared the 16 slings that have been available during your career, 17 the pore size of that, compared with other types of 18 mesh, say, the Ultrapro, as far as pore size goes 19 for the safety of a sling? 20 MR. RUMANEK: Object to the form. 21 BY THE WITNESS: 22 A. I don't know what an Ultrapro is. 23 BY MS. LIU: 24 Q. Okay. Doctor, what meshes are you</p>	<p style="text-align: right;">Page 129</p> <p>1 name of it. I would say I'm most familiar right 2 now with that one because it's what I use on a 3 regular basis. 4 Q. And, Doctor, have you or do you know of 5 any studies that compare the pore size of these 6 types of pelvic organ prolapse meshes compared with 7 the midurethral sling of the TVT? 8 MR. RUMANEK: Object to the form. 9 BY THE WITNESS: 10 A. I don't know of any studies specifically 11 comparing a sacral colpopexy mesh to a TVT mesh. 12 BY MS. LIU: 13 Q. And, so, you would not be able to say 14 whether the pore size of, say, the BSC mesh that 15 you're using compared with the pore size of the TVT 16 as far as safety goes in a midurethral sling, is 17 that correct? 18 MR. RUMANEK: Object to the form of the 19 question. 20 BY THE WITNESS: 21 A. No, that's not correct. Both of them 22 are Amid Type 1 meshes with large pore size and 23 both are monofilamentous. Beyond that, I think 24 that there isn't much more that matters to me.</p>

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<p style="text-align: right;">Page 130</p> <p>1 Q. So, say, for example, the pore size of 2 the TVT is slightly over 1,000 microns, is that 3 correct? That's what you have in your report? 4 MR. RUMANEK: Object to the form. 5 BY THE WITNESS: 6 A. That is correct. 7 BY MS. LIU: 8 Q. So, that's approximately 1 millimeter, 9 is that correct? 10 A. Um-hmm. 11 MR. RUMANEK: Object to the form. 12 BY MS. LIU: 13 Q. Now -- can you say yes or no? 14 A. Yes. 15 Q. Okay. So, do you know how that 16 1 millimeter is measured? 17 A. Like with a ruler, is that what you're 18 asking? 19 Q. Sorry. No. Do you know like as far as 20 the pore size goes where the measurement is taken? 21 A. My understanding is from one aspect of 22 the repeated pattern to the beginning of the next. 23 So -- 24 Q. What shape is the pore in a TVT mesh?</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. Okay. And, Doctor, have you read in any 2 literature or any kind of internal documents that 3 state, you know, pore size is between, say, 2 and 4 4 millimeters would be safer than the 1 millimeter 5 pore size of the TVT? 6 MR. RUMANEK: Object to the form. 7 BY THE WITNESS: 8 A. I have not. I have -- I know that there 9 are some ultra-lightweight prolapse meshes that 10 have pore sizes of that caliber. But in terms of 11 projecting that on to whether or not the TVT would 12 be a safer device if it had that size of pores, I 13 would say I've never heard that before or read that 14 before and I can't imagine that that's true. 15 BY MS. LIU: 16 Q. And when you say you can't imagine that 17 that's true, is that just based on speculation? 18 MR. RUMANEK: Object to the form. 19 BY THE WITNESS: 20 A. No, I think when you're talking about 21 the efficacy of a midurethral sling, my sense of 22 what's required of the material is based on my 23 experience of having placed these and then taking 24 care of patients who have them implanted.</p>
<p style="text-align: right;">Page 131</p> <p>1 A. I don't know the exact shape of it. 2 Like I said, I haven't looked at it underneath a 3 microscope to know whether it's round or orthogonal 4 or... 5 Q. And -- 6 MR. RUMANEK: We have been going now over two 7 hours. I don't know when a good stopping point is. 8 MS. LIU: Sure. We can do a stop. 9 (WHEREUPON, a recess was had 10 from 11:22 to 11:33 a.m.) 11 BY MS. LIU: 12 Q. Doctor, last we were talking about the 13 pore size of the TVT sling. 14 A. Yes. 15 Q. And I believe we were talking about how 16 it's measured from point A to point B. You 17 mentioned you didn't know whether or not it was a 18 circular type of measurement. Do you know how it 19 was measured? 20 A. I really don't. I've never read about 21 that particular aspect of measuring pore size. 22 Q. And -- 23 A. I was assuming it was the actual pore 24 size but, you know, the dimension of the hole.</p>	<p style="text-align: right;">Page 133</p> <p>1 And I have used the ultra-lightweight 2 meshes in sacral colpopexy before and have found 3 them to be prohibitively flimsy. They've torn 4 during handling in the operating room and that 5 concerns me with respect to function. 6 Obviously you don't want to place any 7 material into a patient if it's not going to help 8 them. 9 And I believe that a really large pore 10 size would probably not be able to accomplish the 11 task of creating a good supportive scaffold for the 12 urethra at the midpoint the way the midurethral 13 sling is supposed to. 14 Q. And have you tested that theory? 15 A. I feel like my clinical experience 16 satisfies my curiosity about that, but I've never 17 conducted an experiment. 18 I have handled ultra-lightweight meshes 19 at the time of sacral colpopexy and have found them 20 to be frustratingly flimsy. 21 Q. Doctor, have you heard of a product or a 22 mesh called Pronova? 23 A. No. 24 Q. Have you -- sorry. Strike that.</p>

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<p style="text-align: right;">Page 138</p> <p>1 Do you see that? Up top on to the left 2 corner. 3 A. Yes. 4 Q. Okay. Do you see that there are several 5 pages of internal documents that are listed on your 6 reliance list? 7 A. Yes. 8 Q. But you didn't actually rely on them, is 9 that correct? 10 A. That's correct. 11 Q. Did you rely on the two or the three 12 that you reviewed in generating your report? 13 A. Well, like I said, I read them after I 14 generated the report. So, no. 15 Q. So, you didn't rely on any internal 16 documents in generating your report? 17 A. No, I didn't think they were relevant to 18 what I was writing. 19 Q. Were they provided to you prior to 20 generating your report? 21 A. I mean, I -- I bet I had -- I bet they 22 were included in some of the materials that Butler 23 Snow sent me. They're just not helpful to what 24 I -- what I was writing.</p>	<p style="text-align: right;">Page 140</p> <p>1 of the device. 2 Q. So, if the biomaterial engineers who 3 designed the product tested the product or later on 4 developed or later on -- strike that -- or later on 5 gathered information that related to the safety of 6 its product, you wouldn't find that that would be 7 relevant to your analysis? 8 MR. RUMANEK: Object to the form. 9 BY THE WITNESS: 10 A. I think it might be relevant but not 11 necessary because I have so much other data that, 12 you know, comes from the peer-reviewed body of 13 literature. I just can't imagine that that one 14 memo would change what I already know based on a 15 systematic review type level evidence. 16 BY MS. LIU: 17 Q. So, you're basically saying that in 18 any -- even if you had the entire body of internal 19 documents, you wouldn't consider them in generating 20 your report, is that correct? 21 MR. RUMANEK: Object to the form. 22 BY THE WITNESS: 23 A. If I had -- I can't say that. I mean, I 24 didn't read them all, you know. If there's a</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. So, you didn't review them prior to 2 writing your report? 3 A. Correct. 4 Q. Now, do you know how Butler Snow 5 determined the internal documents to send to you? 6 A. No. 7 Q. And you said you did not feel that they 8 were relevant. If you hadn't reviewed them, how 9 come you didn't feel that they were relevant? 10 MR. RUMANEK: Object to the form. 11 BY THE WITNESS: 12 A. Well, you know, in -- I was charged with 13 creating a document that talked about my opinions 14 related to the safety and efficacy of the TVT 15 especially as it compares to its alternatives. 16 And I don't think that -- I mean, I 17 think that the really robust scientific literature 18 about these devices is almost overwhelming in 19 quantity. I had my hands full with that and that I 20 do think is relevant to the safety and efficacy of 21 the device. 22 What different members of a corporation 23 are saying to each other about that device is not 24 helpful in my opinion about the safety and efficacy</p>	<p style="text-align: right;">Page 141</p> <p>1 specific document you're referring to, I could look 2 at that. 3 But I, you know -- I kind of hold the 4 literature that I base my opinions on to a pretty 5 high standard and that's peer review and scientific 6 rigor, and I had that in the documents that were 7 available to me that I'm already familiar with and 8 I relied on those. 9 Q. But you did not consider or rely on any 10 internal documents in generating your general TVT 11 and TVT Exact report, is that correct? 12 A. That's correct. 13 MR. RUMANEK: Object to form. 14 BY MS. LIU: 15 Q. So, if internally Ethicon felt that 16 there was a better mesh than the TVT mesh for the 17 midurethral retropubic sling and felt that -- 18 sorry. Strike that. 19 If internally there were documents that 20 show that Ethicon had believed, their material 21 engineers had believed there was a better mesh out 22 there over the TVT, you would not have considered 23 that information, is that correct? 24 MR. RUMANEK: Object to the form. She's</p>

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<p style="text-align: right;">Page 150</p> <p>1 BY MS. LIU: 2 Q. Over the course of your 14 years. 3 A. I'd say I've read about half of this. 4 Q. And did you rely on any of this 5 material, the ones that you have read, in 6 generating your report? 7 A. Yes. 8 Q. But not all of the materials in here, is 9 that correct? 10 A. Right, yes. 11 Q. Now, Doctor, you mentioned that you rely 12 on medical literature in generating your report. 13 And that's basically what you relied on, is that 14 correct? 15 A. Yes. 16 MR. RUMANEK: Object to the form. 17 BY MS. LIU: 18 Q. And in generating your report based on 19 that medical literature, what -- how do you usually 20 get your literature? 21 A. Lots of different ways. I receive 22 certain journals or the table of contents of 23 certain journals every month, so I know what's 24 being published, in the Green Journal, the Gray</p>	<p style="text-align: right;">Page 152</p> <p>1 generating your report, how did you choose which 2 pieces of literature to cite to? 3 A. I selected the best quality study that I 4 felt best supported the point that I was trying to 5 make. 6 Q. And, so, you specifically chose 7 literature that supported your viewpoint, is that 8 correct? 9 MR. RUMANEK: Object to the form. 10 BY THE WITNESS: 11 A. Well, I mean, I think it only makes 12 sense that if you're trying to make a point, that 13 you don't just state the point, that you actually 14 provide literature that that's true. 15 And sometimes I would provide, you know, 16 references to literature that posited the opposite 17 of the point that I was trying to make and then 18 another reference that would disprove that. 19 BY MS. LIU: 20 Q. So, as far as the literature that was 21 opposite of your viewpoint, what kind of weight did 22 you give it? 23 MR. RUMANEK: Object to the form. 24 BY THE WITNESS:</p>
<p style="text-align: right;">Page 151</p> <p>1 Journal, the Gold Journal, International 2 Urogynecology Journal. 3 And then twice a year there are national 4 conferences that I attend that, you know, highlight 5 a lot of new developments and kind of let you know 6 what's going to be coming down the pike in the 7 literature because a lot of the articles start as 8 research projects that get presented at national 9 conferences. 10 And then, you know, I work with people 11 in my field who talk about articles that they've 12 read and we send articles to each other frequently 13 and... 14 Q. In generating your report did you read 15 all the literature that Ethicon sent to you? 16 A. No. 17 Q. Do you know how Ethicon generated its 18 literature list to send to you? 19 MR. RUMANEK: Object to the form and the 20 characterization. 21 BY THE WITNESS: 22 A. No. 23 BY MS. LIU: 24 Q. When you read the literature for</p>	<p style="text-align: right;">Page 153</p> <p>1 A. What do you mean? 2 BY MS. LIU: 3 Q. So, you mentioned just now that you 4 would cite to literature that supported your 5 viewpoint and then you also sometimes would cite to 6 literature that was opposite of your viewpoint and 7 then after that you would cite to literature that 8 disproves the literature that was opposite your 9 viewpoint. 10 So, my question is: In that literature 11 that you reviewed that was opposite your viewpoint, 12 how did you determine whether or not it was a 13 relevant study for you? 14 MR. RUMANEK: Object to the form. 15 BY THE WITNESS: 16 A. Well, I mean, scientific discovery is a 17 linear process and these articles were published 18 along the course of that linear process. So, you 19 know, what was published in 2016 wasn't available 20 in 2008. 21 So, sometimes I'd be describing the 22 progression of a theory or the progression of 23 knowledge as it related, for example, to the 24 materials used for midurethral sling. There were</p>

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<p style="text-align: right;">Page 154</p> <p>1 many that were tried before the Type 1, Amid Type 1 2 polypropylene meshes. And so we had descriptions 3 of what happened with some of those materials and 4 then what happened next and then what happened next 5 and then what happened next. 6 Q. So, Doctor, when you saw publications, 7 peer-reviewed publications, that described 8 polypropylene slings causing chronic pain, what 9 kind of consideration did you give that in 10 generating your report? 11 MR. RUMANEK: Object to the form. 12 BY THE WITNESS: 13 A. I didn't see any publications that 14 convinced me that the mesh caused chronic pain. 15 BY MS. LIU: 16 Q. But you do agree that there is 17 literature out there that states that midurethral 18 slings can cause chronic pain, is that correct? 19 A. Again, I think that it's safe to say 20 that the surgeries used to implant the slings, some 21 of those patients that underwent those surgeries 22 developed chronic pain. I don't think anyone can 23 definitively say that the midurethral sling caused 24 that pain.</p>	<p style="text-align: right;">Page 156</p> <p>1 articles? 2 A. Sometimes. 3 Q. But other times you do not? 4 A. It depends on the nature of the -- I 5 mean, there are many studies that are funded by 6 devices and device companies, but they are 7 completely investigator-managed studies, 8 investigator-designed studies. So, the company 9 doesn't actually have any input on the study design 10 or the conducting of the study. I think that those 11 are still scientifically legitimate. 12 Q. So, the studies that would have 13 investigator control that you mentioned, you know, 14 of the investigation, if those conflict of 15 interests were from, say, doctors that were 16 consultants or that had, you know, been preceptors 17 for a medical device company, would that be 18 considered any kind of, in your mind, would that be 19 considered input from the company? 20 MR. RUMANEK: Object to the form. 21 BY THE WITNESS: 22 A. Maybe. But again, you know, there is -- 23 there has to be scientific merit to the study. The 24 data have to be supporting the conclusion that</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. So, now in all of the literature that 2 you reviewed that was opposite from you, none of 3 them convinced you of that the polypropylene 4 midurethral sling could cause chronic pain, is that 5 correct? 6 MR. RUMANEK: Object to the form, 7 mischaracterizes testimony. 8 BY THE WITNESS: 9 A. I was not convinced. 10 BY MS. LIU: 11 Q. Did you give it any consideration? 12 A. Of course. 13 Q. What kind of consideration did you give 14 it? 15 A. I mean, I think scientific 16 consideration, you know, what is the scientific 17 merit of the study, do the data produced support 18 the conclusions or not. 19 Q. And -- 20 MR. RUMANEK: Object to form. 21 BY MS. LIU: 22 Q. And, Doctor, when you give weight to an 23 article, do you consider whether or not there are 24 conflicts of interest in the authors of those</p>	<p style="text-align: right;">Page 157</p> <p>1 they're trying to make. And I still think that it 2 would probably be irresponsible to throw out all 3 studies that, you know, are funded through a device 4 company. 5 Q. And you just said maybe. Was this 6 something you thought about at all when you 7 generated your report? 8 MR. RUMANEK: Object to the form. 9 BY THE WITNESS: 10 A. I mean, I relied on data that I believe 11 to be sound from studies that I believe to be 12 well-designed. 13 BY MS. LIU: 14 Q. And you believe them to be 15 well-designed. Did you look into whether or not 16 there were conflicts of interest at the time you 17 considered them to be well-thought-of, designed 18 studies? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. I mean, not past what it would have said 22 on the front page of the -- some of the studies 23 that I read and cited are funded studies. Some of 24 them are funded by, you know, NIH and some of them</p>

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<p style="text-align: right;">Page 198</p> <p>1 MR. RUMANEK: Object to the form. 2 BY THE WITNESS: 3 A. No. I mean, there is so much clinical 4 evidence and peer-reviewed evidence to suggest that 5 the pore size is exactly right. If we were 6 concerned about the pore size being too small, then 7 by definition we would be seeing a lot of infected 8 mesh and the truth is we're just not seeing that. 9 Clinically I have not seen it. I don't think I've 10 ever been able to definitively say that a Type 1 11 polypropylene mesh is infected. 12 BY MS. LIU: 13 Q. So, what about -- we talked about 14 shrinkage and contraction. So, with shrinkage and 15 contraction, would the pore size -- if Ethicon's 16 own scientists stated that the pore size was 17 insufficient for contraction and shrinkage -- 18 A. Again, I -- 19 Q. Let me finish the question. 20 MR. RUMANEK: Let her ask the question. Let 21 me object. 22 BY MS. LIU: 23 Q. Would that change your opinion? 24 MR. RUMANEK: Object to the form, misstates</p>	<p style="text-align: right;">Page 200</p> <p>1 A. I know the density. I don't know the 2 weight. If you were to discontinue it from its 3 trocars and put it on a scale, I don't know how 4 much it weighs. 5 Q. Do you know what the weight is per, say, 6 centimeter squared? 7 A. I believe it's 100 grams per centimeter 8 squared. 9 Q. And do you believe that to be 10 lightweight? 11 A. No, not lightweight. 12 Q. What weight would you consider that to 13 be? 14 A. I mean, the weight is 100 grams per 15 centimeter cubed. 16 Q. Would you consider -- sorry. Go ahead. 17 Would you consider that to be a 18 heavyweight mesh? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. I guess. I don't know. I don't really 22 consider it to be a heavyweight mesh. But in the 23 classification system, I suppose. 24 BY MS. LIU:</p>
<p style="text-align: right;">Page 199</p> <p>1 the evidence. 2 BY THE WITNESS: 3 A. No. I think that the evidence is -- is 4 what it is. We don't -- we don't just see those 5 things happening. 6 BY MS. LIU: 7 Q. So, even if Ethicon's own internal 8 scientists stated as such, that would not be 9 something that you would rely upon in generating 10 your opinion, is that correct? 11 MR. RUMANEK: Object to the form, 12 mischaracterizes the evidence, asked and answered. 13 BY THE WITNESS: 14 A. I guess it's correct, yes. 15 BY MS. LIU: 16 Q. Now, would it change your opinion if 17 Ethicon's own scientists believe that the Amid 18 study was outdated? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. No. 22 BY MS. LIU: 23 Q. Do you know the weight of the TVT mesh 24 or TVT Exact mesh?</p>	<p style="text-align: right;">Page 201</p> <p>1 Q. Do you believe a lighter weight mesh 2 would have a better safety profile? 3 MR. RUMANEK: Object to the form. 4 BY THE WITNESS: 5 A. I do not. 6 BY MS. LIU: 7 Q. And even if Ethicon's own scientist 8 believe that a lighter weight mesh would have a 9 better safety profile, you would not consider that 10 information in your opinions? 11 MR. RUMANEK: Object to the form. 12 BY THE WITNESS: 13 A. I would not. 14 BY MS. LIU: 15 Q. Have you done any -- have you reviewed 16 any of the testing done by Ethicon? 17 A. No. 18 Q. Do you have any opinions as to whether 19 or not the TVT mesh frays? 20 MR. RUMANEK: Object to the form. 21 BY THE WITNESS: 22 A. I do not believe that it frays when used 23 appropriately in a clinical setting. 24 BY MS. LIU:</p>

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<p style="text-align: right;">Page 206</p> <p>1 Q. If you had seen such a document, would 2 that change your opinion? 3 MR. RUMANEK: She doesn't know because you 4 haven't shown her the document. 5 BY MS. LIU: 6 Q. Assuming that what I am telling you is 7 true. If you were to see that document, would that 8 change your opinion? 9 MR. RUMANEK: Object to the form. 10 BY THE WITNESS: 11 A. I don't know. 12 BY MS. LIU: 13 Q. Do you know what antioxidants are used 14 with the mesh that is weaved into the TVT? 15 A. I don't specifically know which ones are 16 used. 17 Q. And you do agree they use antioxidants, 18 correct? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. Correct. 22 BY MS. LIU: 23 Q. Do you know what the clinical risks of 24 these antioxidants are?</p>	<p style="text-align: right;">Page 208</p> <p>1 antioxidant compound as is produced with the TVT, 2 yes, I believe that it is inert. 3 Q. And how did you form this opinion that 4 it was inert? 5 A. Well, you know, mostly my clinical 6 experience tells me that it's inert and, you know, 7 there are -- there is some recent literature from I 8 think it was even December of 2016, the Thames 9 report shows definitely that it is inert. 10 Q. Now, have you reviewed any internal 11 documents by Ethicon that found microscopic changes 12 to the surface of the mesh after it's been 13 implanted? 14 MR. RUMANEK: Object to the form. 15 BY THE WITNESS: 16 A. Not Ethicon documents that said that, 17 no. 18 BY MS. LIU: 19 Q. And if you had seen Ethicon documents 20 where they've stated they've tested the mesh after 21 implantation and that there are changes to the 22 surface of the mesh, would that change your opinion 23 as to whether or not the polypropylene is inert? 24 MR. RUMANEK: Object to the form,</p>
<p style="text-align: right;">Page 207</p> <p>1 MR. RUMANEK: Object to the form. 2 BY THE WITNESS: 3 A. I don't believe there are any risks to 4 the antioxidants used. 5 BY MS. LIU: 6 Q. And why -- how do you say that? 7 A. Well, my understanding is that the -- 8 there are antioxidants compounded with the mesh 9 material to prevent oxidation of the mesh in situ 10 in vivo and there haven't been any adverse events 11 that come from the antioxidant package per se and 12 so -- but since I can't name the specific 13 antioxidants, I can't tell you their profiles 14 specifically. 15 Q. Now, in your report your opinion is that 16 the polypropylene mesh used to make the TVT or 17 TVT Exact is inert, is that correct? 18 MR. RUMANEK: Where are you referring 19 specifically? 20 BY MS. LIU: 21 Q. Just in your report you've -- you've 22 stated in your report, it's your opinion that the 23 polypropylene mesh is inert, is that correct? 24 A. Well, the polypropylene mesh with the</p>	<p style="text-align: right;">Page 209</p> <p>1 mischaracterizes the evidence. 2 BY THE WITNESS: 3 A. It would not. 4 BY MS. LIU: 5 Q. So, you would not consider any of the 6 tests that Ethicon did during the development and 7 along the lines of them selling the TVT, you 8 wouldn't consider any tests that they did as part 9 of your report? 10 MR. RUMANEK: Object to the form. Are you 11 asking her did she consider it? She said numerous 12 times if you want to show her a document, she will 13 consider it. Are you asking did she consider it? 14 BY MS. LIU: 15 Q. No. My question was if -- you had 16 stated that it wouldn't matter if you had seen 17 these documents, that you would not have considered 18 them in your report. 19 So, what I'm just trying to clarify is 20 that if you had seen tests with results from 21 Ethicon that showed that the polypropylene was not 22 inert, would you have considered that in generating 23 your report? 24 MR. RUMANEK: Object to the form.</p>

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<p style="text-align: right;">Page 210</p> <p>1 BY THE WITNESS:</p> <p>2 A. I mean I think the Thames paper is</p> <p>3 irrefutable, and I have that data. So, I'm not</p> <p>4 sure that there is anything that I could read from</p> <p>5 an internal document from Ethicon that would change</p> <p>6 my mind about that.</p> <p>7 BY MS. LIU:</p> <p>8 Q. And you also in your report noted the</p> <p>9 Material Safety Data Sheet, is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. And you also noted that based on the</p> <p>12 Material Safety Data Sheet, you did not feel as</p> <p>13 though -- that that had any bearing on your use of</p> <p>14 the TVT mesh, is that correct?</p> <p>15 MR. RUMANEK: Object to the form to the extent</p> <p>16 it mischaracterizes what's in the report.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes. Did you want to -- where are you</p> <p>19 in the report?</p> <p>20 BY MS. LIU</p> <p>21 Q. I'm not sure exactly where I am</p> <p>22 because -- but --</p> <p>23 A. There is no page number for you?</p> <p>24 Q. I wasn't looking at it when I was asking</p>	<p style="text-align: right;">Page 212</p> <p>1 Q. And, so, you didn't rely on the MSDS</p> <p>2 when you formed your opinions, is that correct?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Correct. I just want to clarify that I,</p> <p>6 when thinking about the material of the TVT, is not</p> <p>7 a raw polypropylene material. It's actually there</p> <p>8 is additives to it that make it not the same</p> <p>9 material.</p> <p>10 BY MS. LIU:</p> <p>11 Q. And, Doctor, you don't know what</p> <p>12 those -- the added materials are, correct?</p> <p>13 A. I just know that they are --</p> <p>14 MR. RUMANEK: Object to the form.</p> <p>15 BY MS. LIU:</p> <p>16 Q. And, so, you've never tested how these</p> <p>17 antioxidants affect the mesh, correct?</p> <p>18 MR. RUMANEK: Object to the form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Correct. I don't see that that's</p> <p>21 necessary.</p> <p>22 BY MS. LIU:</p> <p>23 Q. And you've never seen any of the test</p> <p>24 results that Ethicon may or may not have done with</p>
<p style="text-align: right;">Page 211</p> <p>1 you the question. So, I'm not sure.</p> <p>2 But in your -- you did reference the</p> <p>3 MSDS, correct?</p> <p>4 MR. RUMANEK: If you need to find it, take the</p> <p>5 time to find it. It's not a memory test.</p> <p>6 BY MS. LIU:</p> <p>7 Q. Let's move on.</p> <p>8 Doctor, have you reviewed the MSDS for</p> <p>9 the -- Ethicon's TVT mesh?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And did you consider the MSDS</p> <p>12 when you drafted your report?</p> <p>13 MR. RUMANEK: Object to the form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Not really, no.</p> <p>16 BY MS. LIU:</p> <p>17 Q. I just found it too.</p> <p>18 A. Yeah.</p> <p>19 Q. So, you did not consider the data that</p> <p>20 was in the MSDS, is that correct?</p> <p>21 MR. RUMANEK: Object to the form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That's correct.</p> <p>24 BY MS. LIU:</p>	<p style="text-align: right;">Page 213</p> <p>1 the antioxidants on the polypropylene mesh for the</p> <p>2 TVT?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Do you mean their own internal studies?</p> <p>6 BY MS. LIU:</p> <p>7 Q. Correct.</p> <p>8 A. No.</p> <p>9 Q. And, so, you didn't consider any of that</p> <p>10 material in generating your report, correct?</p> <p>11 MR. RUMANEK: Object to the form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Right.</p> <p>14 BY MS. LIU:</p> <p>15 Q. Have you seen evidence in the literature</p> <p>16 that shows that the TVT mesh shrinks or contracts?</p> <p>17 MR. RUMANEK: Object to the form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I have seen reports about the complex of</p> <p>20 the mesh and the human tissue into which it's</p> <p>21 implanted shrinking together a small amount, yes.</p> <p>22 BY MS. LIU:</p> <p>23 Q. Did you, when you were researching to</p> <p>24 draft your report, did you run any PubMed searches</p>

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<p style="text-align: right;">Page 222</p> <p>1 have that perspective. 2 BY MS. LIU: 3 Q. So you wouldn't consider yourself to be 4 a polymer expert, correct? 5 MR. RUMANEK: Object to the form, 6 mischaracterizes her testimony. 7 BY THE WITNESS: 8 A. I would say I have an expert level of 9 familiarity with the midurethral sling. 10 BY MS. LIU: 11 Q. From a clinical perspective, correct? 12 A. Correct. 13 Q. Not in the design perspective, correct? 14 MR. RUMANEK: Object to the form. 15 BY THE WITNESS: 16 A. I think I've said that already. 17 BY MS. LIU: 18 Q. And, so, that would be a yes? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. Yes. 22 BY MS. LIU: 23 Q. Now, in the case-specific study or 24 expert reports that you've provided, have you</p>	<p style="text-align: right;">Page 224</p> <p>1 BY MS. LIU: 2 Q. So, you concluded it was surgeon error? 3 MR. RUMANEK: Object to the form. 4 BY THE WITNESS: 5 A. Correct. 6 BY MS. LIU: 7 Q. Did you consider that it could have been 8 the TVT? 9 A. Yes. 10 Q. And what kind of consideration did you 11 give it? 12 A. Well, I gave it I think a scientist's 13 consideration. This is one piece of the puzzle. 14 And you have to ask questions about feasibility, 15 scientific feasibility, of the mesh causing the 16 problems. Is there a mechanism by which that's 17 possible? And the answer is no. 18 Is there a likelihood or a body of 19 evidence that would support the mesh causing these 20 injuries? And the answer is clearly no. 21 Q. So, in your opinion because you believe 22 that the TVT itself is a tool and cannot cause 23 these injuries in these patients, you automatically 24 assume that whenever a patient has complications,</p>
<p style="text-align: right;">Page 223</p> <p>1 concluded that all of them were -- all of the 2 complications that the Plaintiffs had in those 3 cases were not due to the TVT? 4 MR. RUMANEK: Object to the form. 5 BY THE WITNESS: 6 A. I think that would be an 7 oversimplification of all of my expert reports. 8 I think I made this distinction earlier, 9 but I'll make it again, that the TVT is a tool 10 similar to a scalpel or a needle or a suture. It's 11 a surgeon's tool. A surgeon can use most tools to 12 hurt somebody. It's not the tool that's causing 13 the damage. It's the surgeon. 14 BY MS. LIU: 15 Q. So, in every case that you have provided 16 an expert opinion on, you have concluded that it's 17 not the TVT but it's the surgeon that caused the 18 problems? 19 MR. RUMANEK: Object to the form. 20 BY THE WITNESS: 21 A. Insofar as -- I mean, there were really 22 only two of the cases that I reviewed that actually 23 had injuries at all and those two injuries were 24 caused by surgeons.</p>	<p style="text-align: right;">Page 225</p> <p>1 it is not due to the TVT mesh, is that correct? 2 MR. RUMANEK: Object to the form, 3 mischaracterizes her testimony. 4 BY THE WITNESS: 5 A. I mean, I think at some point you're 6 splitting hairs a little bit. You can't -- the 7 mesh can't be placed without a surgery and I 8 believe it's the surgery that causes the injury. 9 BY MS. LIU: 10 Q. Now -- 11 MR. RUMANEK: Hold on. Were you finished? 12 BY THE WITNESS: 13 A. No. I was just going to say that the -- 14 it probably becomes hairsplitting to start to, you 15 know, try to parse out exactly what led to the 16 problem. By definition you can't have a sling 17 implanted without a surgery to implant it. 18 BY MS. LIU: 19 Q. Now, the sling is a medical device that 20 is permanently implanted in the body, is that 21 correct? 22 A. That's correct. 23 Q. And it's meant to be permanent, correct? 24 A. That's correct.</p>

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<p style="text-align: right;">Page 294</p> <p>1 items would be unwanted whether or not there would 2 be a clinical significance, is that correct? 3 MR. RUMANEK: Object to the form, 4 mischaracterizes the testimony. 5 BY THE WITNESS: 6 A. I think it only matters in that there 7 would be clinical significance. So, if there were 8 not any clinical significance to any one of those, 9 then I really wouldn't care about it. 10 BY MS. LIU: 11 Q. But you would still agree that it would 12 be designed not to do any of those things, is that 13 correct? 14 MR. RUMANEK: Object to the form. 15 BY THE WITNESS: 16 A. I think you said that it was not 17 designed to do those things, not that it was 18 designed not to do those things. So, in other 19 words, that wasn't the point of the device. 20 BY MS. LIU: 21 Q. Right. So, regardless of whether or not 22 there is a clinical impact, that wasn't the 23 intention of the device, is that correct? 24 A. Correct.</p>	<p style="text-align: right;">Page 296</p> <p>1 other. So they wouldn't know. 2 Q. And you didn't know, is that correct? 3 A. That's correct. 4 MR. RUMANEK: Object to the form. 5 MS. LIU: I'm going to save the rest of my 6 time for rebuttal. Thank you. 7 Let's go off the record. 8 (WHEREUPON, discussion was had off 9 the record.) 10 EXAMINATION 11 BY MR. RUMANEK: 12 Q. Dr. Collins, I have a few follow-up 13 questions. 14 Do you recall being asked by counsel 15 about the mesh folding or curling as a result of 16 going through where the trocars were placed? 17 A. Yes. 18 Q. Do you recall those questions? 19 A. Yes. 20 Q. Are you aware of any clinical studies or 21 clinical data that have attributed any 22 complications or adverse events to the mesh curling 23 as it goes through the place where the trocar was 24 passed?</p>
<p style="text-align: right;">Page 295</p> <p>1 MR. RUMANEK: Object to the form. 2 BY THE WITNESS: 3 A. The intention of the device was to stop 4 urinary incontinence. 5 BY MS. LIU: 6 Q. And I believe, and I just want to 7 clarify, that in your report you have offered the 8 opinion that the laser-cut mesh and the 9 mechanical-cut mesh are essentially the same 10 clinically, is that correct? 11 MR. RUMANEK: Object to the form. The report 12 speaks for itself. 13 BY THE WITNESS: 14 A. That's correct. 15 BY MS. LIU: 16 Q. Have you ever tracked the complaint 17 rates between the laser-cut mesh and the 18 mechanical-cut mesh? 19 A. No. 20 Q. And how would a physician know whether 21 or not they were implanting a laser-cut or a 22 mechanical-cut mesh? 23 A. I mean, I think that's the point. 24 They're clinically indistinguishable from each</p>	<p style="text-align: right;">Page 297</p> <p>1 MS. LIU: Objection; form. 2 BY THE WITNESS: 3 A. No. 4 BY MR. RUMANEK: 5 Q. Have you had any discussions with 6 colleagues where they have observed any adverse 7 events or complications that they attributed the 8 mesh curling or folding on itself as a result of 9 going through where the trocars passed? 10 MS. LIU: Objection; form. 11 BY THE WITNESS: 12 A. In the retropubic space? 13 BY MR. RUMANEK: 14 Q. Yes. 15 A. No, never. 16 Q. Have you ever seen that in your clinical 17 practice? 18 A. No, never. 19 Q. Do you recall counsel asking you 20 questions about whether or not you had reviewed 21 internal documents, internal Ethicon documents? 22 A. Yes. 23 Q. And do you recall counsel asking you 24 questions about whether you had reviewed deposition</p>

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<p style="text-align: right;">Page 298</p> <p>1 testimony?</p> <p>2 A. Yes.</p> <p>3 Q. I believe you testified that you</p> <p>4 reviewed, you believe, the general depositions of</p> <p>5 Dr. Rosenzweig and Dr. Ostergard, is that correct?</p> <p>6 A. Correct.</p> <p>7 MS. LIU: Objection; mischaracterizes her</p> <p>8 testimony.</p> <p>9 BY MR. RUMANEK:</p> <p>10 Q. Which general Plaintiffs' expert</p> <p>11 depositions did you review?</p> <p>12 A. Dr. Ostergard and Dr. Rosenzweig.</p> <p>13 Q. Okay. And as part of those general</p> <p>14 depositions, did they reference internal Ethicon</p> <p>15 company documents and internal -- deposition</p> <p>16 testimony of Ethicon employees?</p> <p>17 MS. LIU: Objection; form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I can't remember.</p> <p>20 BY MR. RUMANEK:</p> <p>21 Q. If their reports referenced internal</p> <p>22 documents or deposition testimony of internal</p> <p>23 employees, would you have reviewed that in</p> <p>24 preparing your expert report?</p>	<p style="text-align: right;">Page 300</p> <p>1 MS. LIU: Objection; form.</p> <p>2 BY MR. RUMANEK:</p> <p>3 Q. And would you have reviewed what they</p> <p>4 said about the Ethicon employee deposition</p> <p>5 testimony in their general reports?</p> <p>6 A. Yes.</p> <p>7 MS. LIU: Objection; form.</p> <p>8 BY MR. RUMANEK:</p> <p>9 Q. Did anything that was cited in</p> <p>10 Dr. Rosenzweig's expert report or Dr. Ostergard's</p> <p>11 expert report change any of the opinions that you</p> <p>12 formulated in putting together your expert report?</p> <p>13 A. No.</p> <p>14 Q. Did anything that you reviewed in their</p> <p>15 expert reports cause you to request any internal</p> <p>16 documents that they had referenced?</p> <p>17 A. No.</p> <p>18 Q. Did it cause you to go back and look</p> <p>19 through the materials that you had been provided to</p> <p>20 try to find those internal documents?</p> <p>21 A. No.</p> <p>22 Q. Did it cause you to go back and request</p> <p>23 deposition testimony that may have been referenced</p> <p>24 in their reports?</p>
<p style="text-align: right;">Page 299</p> <p>1 MS. LIU: Objection; form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I wouldn't have. I think I would have</p> <p>4 considered that biased and not borne out by the</p> <p>5 evidence in the literature.</p> <p>6 BY MR. RUMANEK:</p> <p>7 Q. Would you have reviewed whatever was</p> <p>8 included in their report with respect to how they</p> <p>9 cited the Ethicon documents or deposition</p> <p>10 testimony?</p> <p>11 A. Sure.</p> <p>12 MS. LIU: Objection. Are you talking</p> <p>13 deposition or report because I think that's where I</p> <p>14 am getting confused.</p> <p>15 MR. RUMANEK: Sorry.</p> <p>16 BY MR. RUMANEK:</p> <p>17 Q. In your review of Dr. Ostergard and</p> <p>18 Dr. Rosenzweig's general reports --</p> <p>19 A. General reports.</p> <p>20 Q. -- if they referenced in their general</p> <p>21 reports Ethicon company documents, would you have</p> <p>22 reviewed what they said about those documents in</p> <p>23 their general report?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 301</p> <p>1 A. No.</p> <p>2 Q. Did it cause you to go back through the</p> <p>3 materials that had been provided to find deposition</p> <p>4 testimony that they had referenced?</p> <p>5 A. No.</p> <p>6 Q. Dr. Collins, do you recall counsel</p> <p>7 asking you some questions about the effective</p> <p>8 porosity of the TVT mesh?</p> <p>9 A. Yes.</p> <p>10 Q. And did any of the questions that she</p> <p>11 asked you about the effective porosity cause you to</p> <p>12 question any of the opinions that are stated in</p> <p>13 your report?</p> <p>14 MS. LIU: Objection; form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No.</p> <p>17 BY MR. RUMANEK:</p> <p>18 Q. Did any of the questions that she asked</p> <p>19 make you believe that you need to go back and</p> <p>20 review additional documents or materials in order</p> <p>21 to maintain the opinions that you've stated in your</p> <p>22 report?</p> <p>23 MS. LIU: Objection; form.</p> <p>24 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 302</p> <p>1 A. No.</p> <p>2 BY MR. RUMANEK:</p> <p>3 Q. In any of the data and literature that</p> <p>4 you've reviewed during the course of your career in</p> <p>5 your practice, have you reviewed any medical</p> <p>6 literature that questioned the safety and</p> <p>7 effectiveness of the TVT sling based on its pore</p> <p>8 size?</p> <p>9 MS. LIU: Objection; form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No.</p> <p>12 BY MR. RUMANEK:</p> <p>13 Q. Have you reviewed any medical literature</p> <p>14 or data that attributed any complications or</p> <p>15 adverse events to an inadequate pore size of the</p> <p>16 TVT?</p> <p>17 A. No.</p> <p>18 Q. Dr. Collins, you were asked a number of</p> <p>19 questions about what Ethicon knew or what Ethicon</p> <p>20 scientists knew. Do you recall counsel asking you</p> <p>21 those questions?</p> <p>22 A. Yes.</p> <p>23 Q. Did counsel show you any of the</p> <p>24 documents that she was purporting to reference in</p>	<p style="text-align: right;">Page 304</p> <p>1 offered that testimony?</p> <p>2 A. Yes, I'm only aware of -- I'm actually</p> <p>3 only aware of characterizing mesh according to</p> <p>4 weight as it pertains to mesh used for pelvic organ</p> <p>5 prolapse and the very lightweight meshes with</p> <p>6 increased pore size are markedly different than the</p> <p>7 TVT mesh.</p> <p>8 Q. Okay. Are you aware of any -- do you</p> <p>9 have an opinion as to whether or not TVT -- the</p> <p>10 mesh used in TVT is lightweight as it compares to</p> <p>11 other midurethral slings?</p> <p>12 MS. LIU: Objection; form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I know that it has a relatively low</p> <p>15 weight compared to other midurethral sling mesh. I</p> <p>16 think I might have been confused about if you were</p> <p>17 to use those meshes then for pelvic organ prolapse.</p> <p>18 I think that they would be considered heavier</p> <p>19 compared to the lightweight meshes that are used</p> <p>20 for prolapse.</p> <p>21 BY MR. RUMANEK:</p> <p>22 Q. And are you aware of any data that</p> <p>23 suggest that using the lighter-weight prolapse</p> <p>24 meshes would be safer or more effective for use in</p>
<p style="text-align: right;">Page 303</p> <p>1 her questioning?</p> <p>2 A. No.</p> <p>3 Q. If counsel had showed you those</p> <p>4 documents, is that something that you would have</p> <p>5 considered relative to the opinions that are set</p> <p>6 forth in your report?</p> <p>7 MS. LIU: Objection; form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. It's hard to say.</p> <p>10 BY MR. RUMANEK:</p> <p>11 Q. Would you have reviewed those to see if</p> <p>12 they impacted your opinions?</p> <p>13 A. Yes, I would have reviewed them.</p> <p>14 Q. I believe counsel asked you about</p> <p>15 whether or not the mesh used in the TVT device,</p> <p>16 whether you would characterize that as heavyweight</p> <p>17 or lightweight mesh. Do you recall those</p> <p>18 questions?</p> <p>19 A. I do.</p> <p>20 Q. Are you aware -- strike that.</p> <p>21 I believe you may have mentioned that it</p> <p>22 could be characterized as heavyweight mesh?</p> <p>23 A. Correct.</p> <p>24 Q. Can you explain what you meant when you</p>	<p style="text-align: right;">Page 305</p> <p>1 a midurethral sling than the TVT mesh?</p> <p>2 MS. LIU: Objection; form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, I don't know of any evidence that</p> <p>5 that's the case. I'd be surprised if it were.</p> <p>6 BY MR. RUMANEK:</p> <p>7 Q. And did you see any evidence in the or</p> <p>8 data in the expert reports of Dr. Rosenzweig or</p> <p>9 Dr. Ostergard that you can recall on that issue?</p> <p>10 MS. LIU: Objection; form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No.</p> <p>13 BY MR. RUMANEK:</p> <p>14 Q. What information would you want --</p> <p>15 strike that.</p> <p>16 Counsel asked you some questions about</p> <p>17 whether certain complications could be associated</p> <p>18 with implanting a TVT mesh. Do you recall those</p> <p>19 questions?</p> <p>20 A. Yes.</p> <p>21 Q. And she asked about chronic pain,</p> <p>22 lifelong dyspareunia, voiding dysfunction, those</p> <p>23 questions. Do you recall those?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 306</p> <p>1 Q. The complications that counsel mentioned</p> <p>2 as being potentially related to a TVT, are those</p> <p>3 also complications that are potentially associated</p> <p>4 with doing a Burch procedure?</p> <p>5 MS. LIU: Objection; form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes.</p> <p>8 BY MR. RUMANEK:</p> <p>9 Q. Are they associated with the</p> <p>10 non-synthetic mesh slings that counsel asked you</p> <p>11 about?</p> <p>12 MS. LIU: Objection; form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Pubovaginal slings?</p> <p>15 BY MR. RUMANEK:</p> <p>16 Q. Yes.</p> <p>17 A. Yes.</p> <p>18 Q. Are you aware of any surgical procedure</p> <p>19 to treat stress urinary incontinence that wouldn't</p> <p>20 carry a risk of potential chronic pain or</p> <p>21 dyspareunia or voiding dysfunction?</p> <p>22 MS. LIU: Objection; form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I can't think of one.</p>	<p style="text-align: right;">Page 308</p> <p>1 A. Yes.</p> <p>2 BY MR. RUMANEK:</p> <p>3 Q. And do you have any opinions as to how</p> <p>4 the safety of midurethral slings as it relates to</p> <p>5 those complications compares with alternative</p> <p>6 procedures?</p> <p>7 MS. LIU: Objection; form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I believe that the safety profile of the</p> <p>10 TVT midurethral sling is better than both the Burch</p> <p>11 and the pubovaginal sling with respect to all of</p> <p>12 those complications.</p> <p>13 BY MR. RUMANEK:</p> <p>14 Q. And what is the basis for that opinion?</p> <p>15 A. Well, there have been trials testing</p> <p>16 this. We have the Ward-Hilton trial. We have --</p> <p>17 we know baseline rates of all of these</p> <p>18 complications from large trials like TOMUS, SISTER,</p> <p>19 that even if they weren't compared head-to-head, we</p> <p>20 have numbers of women who experience these</p> <p>21 complications. And I think every time you look at</p> <p>22 it you will see that TVT is safer.</p> <p>23 Q. And you've reviewed Dr. Rosenzweig's</p> <p>24 general report as well as Dr. Ostergard's general</p>
<p style="text-align: right;">Page 307</p> <p>1 BY MR. RUMANEK:</p> <p>2 Q. Dr. Collins, have you reviewed the</p> <p>3 medical literature and data as it relates to the</p> <p>4 complications that counsel asked you about?</p> <p>5 A. Yes.</p> <p>6 Q. With respect to pain, have you reviewed</p> <p>7 medical literature that discusses complication</p> <p>8 rates associated with pain?</p> <p>9 A. Yes.</p> <p>10 Q. And TVT -- and midurethral slings?</p> <p>11 A. Yes.</p> <p>12 Q. Have you reviewed medical literature</p> <p>13 that discusses complication rates of dyspareunia</p> <p>14 following midurethral slings?</p> <p>15 A. Yes.</p> <p>16 Q. Have you reviewed medical literature</p> <p>17 that discusses complication rates of voiding</p> <p>18 dysfunction after midurethral slings?</p> <p>19 A. Yes.</p> <p>20 Q. Have you read medical literature that</p> <p>21 discusses other known complications associated with</p> <p>22 midurethral slings?</p> <p>23 MS. LIU: Objection; form.</p> <p>24 BY THE WITNESS:</p>	<p style="text-align: right;">Page 309</p> <p>1 reports. Do you recall those reports talking about</p> <p>2 potential cytotoxicity associated with</p> <p>3 polypropylene used in the TVT and TVT Exact?</p> <p>4 A. Yes.</p> <p>5 Q. And based on your review of the data in</p> <p>6 the medical literature have you found any evidence</p> <p>7 that there are any adverse events or complications</p> <p>8 reported in the literature related to cytotoxicity?</p> <p>9 MS. LIU: Objection; form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I have not. Sorry. I have not.</p> <p>12 BY MR. RUMANEK:</p> <p>13 Q. Counsel asked you a number of questions</p> <p>14 about whether you are an expert in chemistry,</p> <p>15 whether you're an expert in chemical engineering,</p> <p>16 whether you're an expert in design of medical</p> <p>17 devices.</p> <p>18 Do you remember that series of questions</p> <p>19 where she asked you whether you're an expert in a</p> <p>20 certain field?</p> <p>21 A. Yes.</p> <p>22 Q. Dr. Collins, do you have expertise as it</p> <p>23 relates to the opinions that you've given in your</p> <p>24 report?</p>

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<p style="text-align: right;">Page 310</p> <p>1 MS. LIU: Objection; form. 2 BY THE WITNESS: 3 A. Yes. 4 BY MR. RUMANEK: 5 Q. And to the extent that any of the 6 opinions that you've given in your report could be 7 characterized as relating to chemistry or chemical 8 engineering or polymers, do you believe that you 9 have expertise in order to offer those opinions? 10 MS. LIU: Objection; form. 11 BY THE WITNESS: 12 A. I do. 13 BY MR. RUMANEK: 14 Q. And what would be the basis for your 15 expertise in those areas? 16 A. Clinical experience, familiarity with 17 the data, basic science training for a long time. 18 Q. And have you in your practice evaluated 19 and considered different mesh devices? 20 A. Yes. 21 MS. LIU: Objection; form. 22 BY MR. RUMANEK: 23 Q. Have you considered the way different 24 mesh devices are designed?</p>	<p style="text-align: right;">Page 312</p> <p>1 A. I did discuss that briefly. 2 Q. And do you believe that those opinions 3 require you to have written an IFU in order to 4 offer the opinions that you've given? 5 MS. LIU: Objection; form. 6 BY THE WITNESS: 7 A. Absolutely not. 8 BY MR. RUMANEK: 9 Q. Dr. Collins, with respect to the IFUs 10 for the TVT and the TVT Exact device, who is the 11 audience -- I think you mentioned in your response 12 to a question from opposing counsel about who the 13 IFU is written for -- who is the audience, the 14 intended audience of an IFU? 15 A. I believe the surgeons implanting the 16 device are the audience. 17 Q. And I'm just going to read from the IFU, 18 a section from the IFU. 19 It says, "It is not a comprehensive 20 reference to surgical technique for correcting 21 stress urinary incontinence. The device should 22 only be used by physicians trained in the surgical 23 treatment of stress urinary incontinence and 24 specifically implanting the TVT device. These</p>
<p style="text-align: right;">Page 311</p> <p>1 A. Yes. 2 Q. Have you considered the way that how 3 those mesh devices are designed may impact your 4 patients in your clinical outcomes? 5 MS. LIU: Objection; form. 6 BY THE WITNESS: 7 A. Yes. 8 BY MR. RUMANEK: 9 Q. Do you believe that you have expertise 10 in order to offer opinions about the design of the 11 TVT and TVT Exact as it relates to your clinical 12 practice, the medical literature and the outcomes 13 that you've observed? 14 MS. LIU: Objection; form. 15 BY THE WITNESS: 16 A. Yes. 17 BY MR. RUMANEK: 18 Q. Counsel also asked you whether you had 19 been involved in writing IFUs. Do you recall those 20 questions? 21 A. I do. 22 Q. Have you offered opinions related to the 23 communication of risk information in your expert 24 report?</p>	<p style="text-align: right;">Page 313</p> <p>1 instructions are recommended for general use of the 2 device. Variations in use may occur in specific 3 procedures due to individual technique and patient 4 anatomy." 5 Do you recall reviewing that language in 6 the IFU for the TVT? 7 A. Yes. 8 Q. And is that consistent with the audience 9 that you understand the IFU to be written to? 10 MS. LIU: Objection; form. 11 BY THE WITNESS: 12 A. Yes. 13 BY MR. RUMANEK: 14 Q. What does it mean for a -- what is your 15 understanding of the meaning where it says that the 16 device should only be used by physicians trained in 17 the surgical treatment of stress urinary 18 incontinence and specifically implanting the TVT 19 device? 20 A. My understanding of that is that there 21 should be a baseline familiarity with the anatomy 22 of continence, female pelvic anatomy, experience 23 with other procedures to correct stress urinary 24 incontinence, and then there should be specific</p>

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<p style="text-align: right;">Page 322</p> <p>1 at the end about, you know, whether or not a doctor 2 who relied solely on the IFU would be within the 3 standard of care? Do you remember that 4 questioning? 5 A. Um-hmm. 6 Q. Doctor, where are you licensed to 7 practice? 8 A. Illinois and Indiana. 9 Q. Anywhere else? 10 A. I have had licenses in other states but 11 they're not current now. 12 Q. What other states have you had licenses 13 for? 14 A. Connecticut, New York and then I had a 15 training certificate for Ohio and I think I had a 16 training certificate for New Hampshire too for -- 17 Q. What is a training certificate? 18 A. That just means that you don't have a 19 full license to independently practice. It's meant 20 for people that are residents or fellows who are 21 not practicing independently. 22 Q. Doctor, are you offering an opinion on 23 the standard of care as it relates to all surgeons 24 that implant TVT?</p>	<p style="text-align: right;">Page 324</p> <p>1 Q. Have any medical device manufacturers 2 ever sent you compilations of e-mails or internal 3 documents to review and consider in their products? 4 A. No. 5 Q. Counsel asked you -- opposing counsel 6 asked you some questions about whether or not you 7 were familiar with specific regulations for what 8 was included -- what was needed for an IFU. Do you 9 recall those questions? 10 A. Um-hmm. 11 Q. Dr. Collins, do you have expertise as it 12 relates to what is needed to be included within an 13 IFU from a physician's perspective? 14 MS. LIU: Objection; form. 15 BY THE WITNESS: 16 A. Sure. 17 BY MR. RUMANEK: 18 Q. And what is the basis for that opinion? 19 A. I am a surgeon that implants TVT and 20 there are very few things that I need from an IFU, 21 and I think that most well-trained surgeons are the 22 same in that respect. 23 Q. And putting aside whether or not 24 something is within the, quote-unquote, "standard</p>
<p style="text-align: right;">Page 323</p> <p>1 MR. RUMANEK: Object to the form; overbroad, 2 non-specific. 3 BY THE WITNESS: 4 A. Yes. 5 BY MS. LIU: 6 Q. So, you believe that you are able to 7 offer standard of care opinions on all surgeons for 8 TVT regardless of where they're practicing, is that 9 correct? 10 A. Yes. 11 MS. LIU: I believe that's all the questions 12 that I have right now. 13 MR. RUMANEK: I have got just a few follow-up 14 questions. 15 FURTHER EXAMINATION 16 BY MR. RUMANEK: 17 Q. Dr. Collins, are you aware of any 18 physicians who rely as part of their practice on 19 internal company e-mails with respect to making 20 decisions about which products they're going to 21 employ? 22 A. No. 23 MS. LIU: Objection; form, speculation. 24 BY MR. RUMANEK:</p>	<p style="text-align: right;">Page 325</p> <p>1 of care," are you aware of any physicians who have 2 relied solely on an IFU in order to understand how 3 to implant the TVT or TVT Exact or the 4 complications or potential risks associated with 5 that procedure? 6 A. No. 7 MS. LIU: Objection; form, asked and answered. 8 BY MR. RUMANEK: 9 Q. And have you ever had any discussions 10 with colleagues who have indicated to you that they 11 relied solely on the IFU in order to understand how 12 to perform a surgical procedure or to learn about 13 the complications associated with the surgical 14 procedure? 15 A. No. 16 MS. LIU: Objection; form. 17 BY MR. RUMANEK: 18 Q. Dr. Collins, are you aware of any IFUs 19 that are provided with respect to surgeons 20 performing a Burch procedure? 21 MS. LIU: Objection; form. 22 BY THE WITNESS: 23 A. No. 24 BY MR. RUMANEK:</p>

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<p style="text-align: right;">Page 330</p> <p>1 FURTHER EXAMINATION</p> <p>2 BY MS. LIU:</p> <p>3 Q. Doctor, you reviewed the 2015 IFU, is</p> <p>4 that correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And you testified that you reviewed one</p> <p>7 other IFU but you don't remember the year, is that</p> <p>8 correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And you believe the 2015 IFU is</p> <p>11 sufficient, is that correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Do you believe that the IFUs prior to</p> <p>14 the 2015 is sufficient?</p> <p>15 A. I do.</p> <p>16 Q. Do you remember reading them?</p> <p>17 A. I do.</p> <p>18 Q. Which ones?</p> <p>19 A. Well, I told you I read one other -- I</p> <p>20 remember reading that one. Like I said, I don't</p> <p>21 know which one it was.</p> <p>22 Q. And you don't remember when it came out?</p> <p>23 A. Right. I know it was not the latest</p> <p>24 iteration.</p>	<p style="text-align: right;">Page 332</p> <p>1 I, CORINNE T. MARUT, C.S.R. No. 84-1968,</p> <p>2 Registered Professional Reporter and Certified</p> <p>3 Shorthand Reporter, do hereby certify:</p> <p>4 That previous to the commencement of the</p> <p>5 examination of the witness, the witness was duly</p> <p>6 sworn to testify the whole truth concerning the</p> <p>7 matters herein;</p> <p>8 That the foregoing deposition transcript</p> <p>9 was reported stenographically by me, was thereafter</p> <p>10 reduced to typewriting under my personal direction</p> <p>11 and constitutes a true record of the testimony</p> <p>12 given and the proceedings had;</p> <p>13 That the said deposition was taken</p> <p>14 before me at the time and place specified;</p> <p>15 That the reading and signing by the</p> <p>16 witness of the deposition transcript was agreed</p> <p>17 upon as stated herein;</p> <p>18 That I am not a relative or employee or</p> <p>19 attorney or counsel, nor a relative or employee of</p> <p>20 such attorney or counsel for any of the parties</p> <p>21 hereto, nor interested directly or indirectly in</p> <p>22 the outcome of this action.</p> <p>23 It was requested before completion of</p> <p>24 the deposition that the witness, SARAH ABBIE</p> <p>COLLINS, M.D., have the opportunity to read and</p> <p>sign the deposition transcript.</p> <p>CORINNE T. MARUT, Certified Reporter</p> <p>(The foregoing certification of this</p> <p>transcript does not apply to any</p> <p>reproduction of the same by any means, unless under</p> <p>the direct control and/or supervision of the</p> <p>certifying reporter.)</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. Did you read the one that was from 2000?</p> <p>2 A. I don't know.</p> <p>3 Q. Or 2002?</p> <p>4 A. Like I said, I don't know the year.</p> <p>5 Q. Okay. So, would you be able to</p> <p>6 confidently testify that each and every iteration</p> <p>7 of the IFU was sufficient if you haven't read them</p> <p>8 all?</p> <p>9 A. I can tell you the ones I've read are</p> <p>10 certainly sufficient.</p> <p>11 Q. And you definitively know 2015 but you</p> <p>12 don't know the other one, correct?</p> <p>13 A. Correct.</p> <p>14 MS. LIU: That's it. No further questions.</p> <p>15 THE REPORTER: Signature?</p> <p>16 MR. RUMANEK: We'll at least reserve the right</p> <p>17 for her to read and sign.</p> <p>18 (Time Noted: 3:49 p.m.)</p> <p>19 FURTHER DEPONENT SAITH NAUGHT.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 333</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections. You</p> <p>5 should state the reason in the appropriate space on</p> <p>6 the errata sheet for any corrections that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet, which</p> <p>11 will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the</p> <p>15 deposition transcript by you. If you fail to do</p> <p>16 so, the deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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